

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arthur M. Krieg et al.  
Serial No: Not yet assigned  
Confirmation No:  
Filed: Herewith  
For: IMMUNOMODULATORY OLIGONUCLEOTIDES  
  
Examiner: Not yet assigned  
Art Unit: Not yet assigned

---

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application (copies enclosed with parent patent applications US Serial No.: 10/690,495, 09/415,142 or 08/386,063 except 10/690,495, a copy of which is enclosed herewith, C1039-70083US01 through 70083US07, are identical to the parent and therefore copies are not enclosed):

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70013US00	09/776,479	2/2/01	Bratzler et al.
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70021US00	09/949,194	9/7/01	Peterson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70038US01	10/735,592	12/11/03	Krieg et al.
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,716	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/455,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/668,050	9/22/03	Bratzler et al.
C1039.70020US00	09/337,584	6/21/99	Krieg et al.
C1039.70022US00	09/337,893	6/21/99	Krieg
C1039.70021US01	10/719,493	11/21/03	Krieg et al.
C1039.70035US00	09/669,187	09/25/00	Krieg et al.
C1039.70036US00	09/559,140	4/27/00	Noll et al.
C1039.70041US00	09/655,319	9/5/00	Krieg et al.
C1039.70042US00	09/630,319	7/31/00	Krieg et al.
C1039.70043US00	09/629,477	7/31/00	Krieg et al.
C1039.70044US00	09/672,126	9/27/00	Hartmann et al.
C1039.70048US00	09/818,918	3/27/01	Krieg et al.
C1039.70048US01	10/769,282	1/30/04	Krieg et al.
C1039.70049US00	09/824,468	04/02/01	Krieg et al.
C1039.70052US00	09/888,326	6/22/01	Weiner et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70058US00	10/023,909	12/18/01	Davis et al.

Serial No.:

- 3 -

Art Unit:

Docket Number	Serial Number	Filing Date	Inventor(s)
C1039.70060US00	10/112,653	3/29/02	Krieg et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
C1039.70069US00	10/314,578	12/9/02	Krieg et al.
C1039.70070US00	10/382,822	3/6/03	Krieg et al.
C1039.70071US00	10/435,656	5/9/03	Krieg et al.
C1039.70072US00	10/434,696	5/9/03	Davis et al.
C1039.70073US00	10/743,625	12/22/03	Krieg et al.
C1039.70075US00	10/613,916	7/3/03	Krieg et al.
C1039.70077US00	10/619,279	7/14/03	Krieg
C1039.70078US00	10/627,331	7/25/03	Krieg et al.
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	10/631,676	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg et al.
C1039.70083US01	10/769,626	1/30/04	Krieg et al.
C1039.70083US02-07	TBD	Herewith	Krieg et al.
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1040.70006US00	09/316,199	5/21/99	McCluskie et al.
C1040.70010US00	09/768,012	1/22/01	Davis et al.
C1041.70002US00	09/241,653	2/2/99	Wagner et al.
C1041.70005US00	09/355,254	7/23/99	Wagner et al.
C1041.70010US00	09/786,436	9/3/99	Wagner et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.
C1041.70040US00	10/666,844	9/19/03	Lipford et al.

Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Arthur M. Krieg et al., *Applicant*

By:   
Helen C. Lockhart, Ph.D., Reg. No. 39,248  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No. C1039.70083US06

Date: February 2, 2004

**XNDDX**

771980

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06			
				FILING DATE: Herewith		CONFIRMATION NO.:			
				APPLICANT: Arthur M. Krieg et al.					
				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned			
Sheet	1	of	7						

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*	2,215,233		Ruskin	09-17-1940
	*	3,911,117		Ender	10-07-1975
	*	3,914,450		Robbins et al.	10-21-1975
	*	4,544,559		Gil et al.	10-01-1985
	*	4,741,914		Kimizuka et al.	05-03-1988
	*	4,758,553		Ogoshi	07-19-1988
	*	4,806,376		Saeki et al.	02-21-1989
	*	4,963,387		Nakagawa et al.	10-16-1990
	*	4,956,296		Fahnestock	09-11-1990
	*	4,994,442		Gil et al	02-19-1991
	*	5,066,500		Gil et al.	11-19-1991
	*	5,231,085		Alexander et al.	07-27-1993
	*	5,234,811		Beutler et al.	08-10-1993
	*	5,268,365		Rudolph et al.	12-07-1993
	*	5,288,509		Potman et al.	02-22-1994
	*	5,488,039		Masor et al.	01-30-1996
	*	5,492,899		Masor et al.	02-20-1996
	*	5,585,479		Hoke et al.	12-17-1996
	*	5,591,721		Agrawal et al.	01-07-1997
	*	5,602,109		Masor et al.	02-11-1997
	*	5,612,060		Alexander	03-18-1997
	*	5,650,156		Grinstaff et al.	07-22-1997
	*	5,663,153		Hutcherson et al.	09-02-1997
	*	5,679,647		Carson et al.	10-21-1997
	*	5,684,147		Agrawal et al	11-04-1997
	*	5,700,590		Masor et al.	12-23-19*97
	*	5,712,256		Kulkarni et al.	01-27-1998
	*	5,723,335		Hutcherson et al.	03-03-1998
	*	5,756,353		Debs	05-26-1998
	*	5,786,189		Locht et al.	07-28-1998
	*	5,840,705		Tsukuda	11-24-1998
	*	5,895,652		Giampapa	04-20-1999
	*	5,922,766		Acosta et al.	07-13-1999
	*	5,929,226		Padmapriya	07-27-1999
	*	5,976,580		Ivey et al.	11-02-1999
	*	5,980,958		Naylor et al	11-09-1999

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06			
				FILING DATE: Herewith		CONFIRMATION NO.:			
				APPLICANT: Arthur M. Krieg et al.					
				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned			
Sheet	2	of	7						

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*	6,004,534		Langer et al.	12-21-1999
	*	6,022,853		Kuberasampath et al.	02-08-2000
	*	6,031,086		Switzer	02-29-2000
	*	6,191,257		Ledley et al.	02-20-2001
	*	6,194,388	B1	Krieg et al.	02-27-2001
	*	6,207,646	B1	Krieg et al.	03-27-2001
	*	6,214,806	B1	Krieg et al.	04-10-2001
	*	6,218,371	B1	Krieg et al.	04-17-2001
	*	6,225,292	B1	Raz et al.	05-01-2001
	*	6,239,116	B1	Krieg et al.	05-29-2001
	*	6,248,720		Mathiowitz et al.	06-19-2001
	*	6,339,068	B1	Krieg et al.	01-15-2002
	*	6,406,705	B1	Davis et al.	06-18-2002
	*	6,429,199	B1	Krieg et al.	08-06-2002
	*	6,498,147		Nerenberg et al.	12-24-2002
	*	6,498,148	B1	Raz	12-24-2002
	*	6,503,533		Korba	01-07-2003
	*	6,514,948	B1	Raz, et al.	02/04/2003
	*	6,534,062	B2	Krieg, et al.	03/18/2003
	*	6,552,006	B2	Raz et al.	04/22/2003
	*	6,562,798	B1	Schwartz	05/13/2003
	*	6,589,940	B1	Raz et al.	07/08/2003
	*	6,610,661	B1	Carson et al.	08/26/2003
	*	6,653,292	B1	Krieg et al.	11/25/2003
	*	US 2001/0046967	A1	Van Nest	11/29/2001
	*	US 2002/0028784	A1	Van Nest	03/07/2002
	*	US 2002/0055477	A1	Nest	05/09/2002
	*	US 2002/0098199	A1	Nest et al.	07/25/2002
	*	US 2002/0107212	A1	Van Nest et al.	08/08/2002
	*	US 2002/0142978	A1	Van Nest et al.	10/03/2002
	*	US 2002/0156033	A1	Raz et al.	10/24/2002
	*	US 2003/0022852	A1	Van Nest et al.	01/30/2003
	*	US 2003/0049266	A1	Bratzler et al.	03/13/2003
	*	US 2003/0050263	A1	Fearon et al.	03/13/2003
	*	US 2003/0059773	A1	Van Nest et al.	03/27/2003

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06			
				FILING DATE: Herewith		CONFIRMATION NO.:			
				APPLICANT: Arthur M. Krieg et al.					
				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned			
Sheet	3	of	7						

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*	US 2003/0078223	A1	Krieg et al.	04/24/2003
	*	US 2003/0092663	A1	Raz et al.	05/15/2003
	*	US 2003/0109469	A1	Raz	06/12/2003
	*	US 2003/0119773	A1	Carson et al.	06/26/2003
	*	US 2003/0129251	A1	Raz et al.	07/10/2003
	*	US 2003/0133988	A1	Van Nest et al.	07/17/2003
	*	US 2003/0143213	A1	Fearon et al.	07/31/2003
	*	US 2003/0147870	A1	Raz et al.	08/07/2003
	*	US 2003/0175731	A1	Raz et al.	09/18/2003
	*	US 2003/0186921	A1	Rearon et al	10/02/2003
	*	US 2003/0199466	A1	Fearon et al.	10-23-2003
	*	US 2003/0212028	A1	Raz et al.	11-13-2003
	*	US 2003/0216340	A1	Van Nest et al.	11-20-2003

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	**	JP	56-008307			01-28-1981	
	**	JP	60-120962			06-28-1985	
	**	EPO	0 178 267 A2			04-16-1986	
	**	JP	62-025960			02-03-1987	
	**	JP	62-148428			07-02-1987	
	**	JP	224259			10-02-1987	
	**	GB	2 216 416 A			11-10-1989	
	**	PCT	US91/05815			08-14-1991	
	**	PCT	US91/01327			09-05-1991	
	**	EP	0 468 520 A3			01-29-1992	
	**	PCT	0 216 133 B1			07-28-1993	
	**	FR	2692897			12-31-1993	
	**	PCT	US94/02471			03-07-1994	
	**	EP	0 302 758 B1			03-16-1994	
	**	PCT	WO95/26204			10-1995	
	**	PCT	WO96/02555			02-01-1996	
	**	JP	8051953			02-27-1996	
	**	JP	8187059			07-23-1996	
	**	JP	9019276			01-21-1997	

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06			
				FILING DATE: Herewith		CONFIRMATION NO.:			
				APPLICANT: Arthur M. Krieg et al.					
				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned			
Sheet	4	of	7						

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	**	CN	1141740A			02-05-1997	
	**	PCT	WO97/42975			11-1997	
	**	CN	1169434			01-07-1998	
	**	JP	10108655			04-28-1998	
	**	PCT	WO98/49348			11-05-1998	
	**	CN	1211443			03-24-1999	
	**	PCT	WO99/37151			07-29-1999	
	**	WO	98/16247	A1	Regents of the University of CA	04-23-1998	
	**	WO	99/11275	A2	Regents of the University of CA	03-11-1999	
	**	WO	99/62923	A2	Dynavax Tech. Corp	12/09/1999	
	**	WO	00/20039	A1	Regents of the University of CA	04/13/2000	
	**	WO	00/21556	A1	Dynavax Tech Corp.	04/20/2000	
	**	WO	00/62787	A1	Regents of the University of CA	10/26/2000	
	**	WO	01/02007	A1	The Regents of the Univ. of California	01-11-2001	
	**	WO	01/12804	A2	Hybridon, Inc.	02-22-2001	
	**	WO	01/12223	A2	Dynavax Tech. Corp.	02-22-2001	
	**	WO	01/55341	A2	The Regents of the Univ. of California	08-02-2001	
	**	WO	01/68117	A2	Dynavax Tech. Corp.	09-20-2001	
	**	WO	01/68116	A2	Dynavax Tech. Corp.	09-20-2001	
	**	WO	01/68078	A2	Dynavax Tech. Corp.	09-20-2001	
	**	WO	01/68077	A2	Dynavax Tech. Corp.	09-20-2001	
	**	WO	01/68103	A2	Dynavax Tech. Corp.	09-20-2001	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	**	Anfossi et al. (P.N.A.S., 86, 9, 3379-83, 89, HCAPLUS, AN 1989:475562)		
	**	Agrawal, et al., "Absorption, Tissue Distribution and <i>In Vivo</i> Stability in Rats of a Hybrid Antisense Oligonucleotide Following Oral Administration" <i>Biochemical Pharmacology</i> (1995) 50:4:571-576		
	**	Agrawal, S, "Antisense Oligonucleotides: Toward Clinical Trials", <i>Tibtech</i> (1996) 14:376-387		
	**	Agrawal, S. and Zhang, R., "Pharmacokinetics and Bioavailability of Antisense Oligonucleotides Following Oral and Colorectal Administration in Experimental Animals" <i>Handb. Exp. Pharmacol.</i> (1998) Vol. 131 Antisense Research and Application pp. 525-543		
	**	Agrawal, S. and Zhang, R., "Pharmacokinetics of Oligonucleotides" <i>Ciba Found Symp.</i> (1997) 209:60-78		



<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06			
				FILING DATE: Herewith		CONFIRMATION NO.:			
				APPLICANT: Arthur M. Krieg et al.					
				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned			
Sheet	5	of	7						

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	**	Azad, Raana F. et al., "Antiviral Activity of a Phosphorothioate Oligonucleotide Complementary to RNA of the Human Cytomegalovirus Major Immediate-Early Region," <i>Antimicrobial Agents and Chemotherapy</i> , (1993) 37: 1945-1954.	
	**	Azuma, I., "Biochemical and Immunological Studies on Cellular Components of Tubercle Bacilli," <i>Kekkaku</i> (1992) 67(9):45-55.	
	**	Blaxter et al., "Genes expressed in <i>Brugia malayi</i> infective third stage larvae," <i>Molecular and Biochemical Parasitology</i> , (1996) 77:77-93.	
	***	Bodey et al. "Failure of cancer vaccines: The significant limitation of this approach to immunotherapy" pp. 2665-2676 2000	
	**	Boiarkina, et al., "Dietary supplementa from ground fish meat with DNA for treatment and prophylaxis", <i>Vopr Pitan</i> , (1998); (1):29-31. <u>Abstract</u>	
	**	Branda et al., "Immune Stimulation by an Antisense Oligomer Complementary to the rev gene of HIV-1," <i>Biochemical Pharmacology</i> , (1993) 45(10):2037-2043.	
	**	Chace, et al., "Regulation of Differentiation in CD5+ and Conventional B Cells", <i>Clin. Immunol. and Immunopath</i> , 68(3):327-332 (1993)	
	**	Chu, et al., "CpG Oligodeoxynucleotides Act as Adjuvants That Switch on T Helper 1 (Th1) Immunity", <i>J. Exp. Med.</i> , (1997) 186(10): 1623-1631	
	**	Crystal, "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <i>Science</i> , (1995) 270:404-410.	
	***	Curtis, <i>Biology</i> , Second Edition, pages 638-641	
	**	Davis, et al., "CpG DNA Is A Potent Enhancer Of Specific Immunity In Mice Immunized With Recombinant Hepatitis B Surface Antigen", <i>J. Immunol</i> , (1998) 160:870-876	
	**	Doerfler, et al., "On the Insertion of Foreign DNA into Mammalian Genomes: Mechanism and Consequences" <i>Gene</i> 157:241-245 (1995)	
	***	Etchart et al. "Class I-restricted CTL induction by mucosal immunization with naked DNA encoding measles virus haemagglutinin" pp. 15775761 vol 72, 1998	
	**	Etlinger, "Carrier Sequence Selection -- One Key to Successful Vaccines," <i>Immunology Today</i> , (1992) 13(2):52-55	
	**	Fanslow, et al., "Effect of nucleotide restriction and supplementation on resistance to experimental murine candidiasis", <i>J. Parenter Enteral Nutr.</i> , (1998) 12(1):49-52 <u>Abstract</u>	
	**	Fox, R.I., "Mechanism of Action of Hydroxychloroquine as an antirheumatic Drug," <i>Chemical Abstracts</i> (1994) 120:15, Abstract No. 182630	
	***	Gilboa Immunotherapy of cancer with genetically modified tumor vaccines pp. 101-107 1996	
	**	Hedley et al., "Microspheres containing plasmid-encoded antigens elicit cytotoxic T-cell responses" pp. 365-368, vol. 4 no. 3 1998	
	***	Hohlweg et al., "On the fate of plant other foreign genes upon th uptake in food or after intramuscular injection in mice" 2001, <i>Mol. Genet Genomics</i> , Vol. 265, pages 225-233	
	***	Jones et al. "Poly(DdL-lactide-co-glycolide)-encapsulated plasmid DNA elicits sytemic and mucosal antibody responses to encoded protein after oral administration" pp 814-817, vol. 15, no. 8 1997	
	**	Kataoka T, et al., "Antitumor Activity of Synthetic Oligonucleotides with Sequences from cDNA Encoding Proteins of <i>Mycobacterium bovis</i> BCG," <i>Jpn. J. Cancer Res</i> (1992) 83:244-247.	
	**	Kimura Y, et al., "Binding of Oligoguanylate to Scavenger Receptors Is Required for Oligonucleotides to Augment NK Cell Activity and Induce IFN," <i>J. Biochem</i> (1994) 116(5):991-994	

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06			
				FILING DATE: Herewith		CONFIRMATION NO.:			
				APPLICANT: Arthur M. Krieg et al.					
				GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned			
Sheet	6	of	7						

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	**	Krieg, et al., "CpG Motifs in Bacterial DNA Trigger Direct B-cell Activation", <i>Nature</i> , 374:546-549 (1995)	
	**	Krieg, et al., "Brief Communication: Oligodeoxynucleotide Modifications Determine the Magnitude of B Cell Stimulation by CpG Motifs", <i>Antisense &amp; Nucleic Acid Drug Delivery Development</i> , 6:133-139 (1996)	
	**	Kuchan, et al., "Nucleotides in Infant Nutrition: Effects on Immune Function" <i>Pediatric Nutrition. Pediatr. Adolesc. Med. Basel</i> . Karger (1998) 8:80-94.	
	**	Kulkarni, et al., "Effect of dietary nucleotides on responses to bacterial infections", <i>J. Parenter Enteral. Nutr.</i> , (1986) 10(2):169-71 <u>Abstract</u>	
	**	Kuramoto et al., "Oligonucleotide Sequences Required for Natural Killer Cell Activation," <i>Jpn. J. Cancer Res.</i> , (1992) 83:1128-1131.	
	***	Lehninger, Biochemistry, Second Edition	
	**	Mastrangelo et al., "Gene Therapy for Human Cancer: An Essay for Clinicians," <i>Seminars in Oncology</i> (1996) 23(1):4-21.	
	***	McCluskie et al. "Novel strategies using DNA for the induction of mucosal immunity" pp. 303-325 1999	
	**	Messina et al., "The Influence of DNA Structure on the <i>in vitro</i> Stimulation of Murine Lymphocytes by Natural and Synthetic Polynucleotide Antigens," <i>Cellular Immunology</i> (1993) 147:148-157.	
	**	Messina et al., "Stimulation of <i>in vitro</i> Murine Lymphocyte Proliferation by Bacterial DNA," <i>The Journal of Immunology</i> (1991) 147(6):1759-1764.	
	**	Mottram, et al., "a Novel CDC2-Related Protein Kinase From Leishania Mexicana.LmmCRK1. Is Post-Translationally Regulated During the Life Cycle", <i>J. Biol. Chem.</i> , 268(28):21044-21052 (1993)	
	***	Perspective pp. 155-156 1999	
	***	Ray et al. "Oral pretreatment of mice with immunostimulatory CpG DNA induces reduced susceptibility to listeria monocytogenes." Vol 15, No. 5, pp. A1007 2001	
	**	Ren jun et al. (Zhonghua Zhong Zazhi, 1994, 16, 4, 247-50, HCAPLUS, AN 1995: 198874)	
	**	Sato et al., "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization," <i>Science</i> (1996) 273:352-354.	
	**	Schnell et al., "Identification and Characterization of a Saccharomyces Cerevisiae Gene (PAR1) Conferring Resistance to Iron Chelators," <i>Eur. J. Biochem.</i> (1991) 200:487-493.	
	**	Shubbert, et al., "Ingested Foreign (phage M13) DNA Survives Transiently in the Gastrointestinal Tract and Enters the Bloodstream of Mice" <i>Mol. Gen. Genet.</i> (1994) 242:495-504	
	**	Stull et al., "Antigene, Ribozyme and Aptamer Nucleic Acid Drugs: Progress and Prospects," <i>Pharmaceutical Research</i> , (1995) 12(4):465-483.	
	**	Tanaka T. et al., "An Antisense Oligonucleotide Complementary to a Sequence in IG2b Germline Transcripts, Stimulates B Cell DNA Synthesis, and Inhibits Immunoglobulin Secretion, <i>J. Exp. Med.</i> , (1992) 175:597-607.	
	**	Tokunaga T. et al., "Synthetic Oligonucleotides with Particular Base Sequences from the cDNA Encoding Proteins of <i>Mycobacterium bovis</i> BCG Induce Interferons and Activate Natural Killer Cells," <i>Microbiol. Immunol.</i> (1992) 36(1):55-66.	

FORM PTO-1449/A and B (Modified)		APPLICATION NO.:		ATTY. DOCKET NO.: C1039.70083US06	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		FILING DATE: Herewith		CONFIRMATION NO.:	
		APPLICANT: Arthur M. Krieg et al.			
		GROUP ART UNIT: Not yet assigned		EXAMINER: Not yet assigned	
Sheet	7	of	7		

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	**	Tokunaga, "A synthetic Single-stranded DNA, Poly(dG,dC), Induces Interferon-alpha/beta and -gamma, Augments Natural Killer Activity, and Suppresses Tumor Growth," <i>Jpn. J. Cancer Res.</i> (1988) 79(6):682-686.	
	***	Tortora et al. "Oral antisense that targets protein kinase a cooperates with taxol and inhibits tumor growth, angiogenesis, and growth factor production!" Vol.6, pp. 2506-2512 2000	
	**	Wallace et al., "Oligonucleotide Probes for the Screening of Recombinant DNA Libraries,," <i>Methods in Enzymology</i> , (1987) 152:432-442.	
	**	Whalen R., "DNA Vaccines for Emerging Infectious Disease: What If?," <i>Emerging Infectious Disease</i> , (1996) 2(3):168-175.	
	**	Wu G.Y. et al., "Receptor-mediated Gene Delivery and Expression <i>in vivo</i> ," <i>J. Biological Chemistry</i> , (1988) 263:14621-14624.	
	**	Yamamoto S. et al., "DNA from Bacteria, but not from Vertebrates, Induces Interferons, Activates Natural Killer Cells and Inhibits Tumor Growth," <i>Microbiol. Immunol.</i> (1992) 36(9):983-997.	
	**	Yamamoto S. et al., "Mode of Action of Oligonucleotide Fraction Extracted from <i>Mycobacterium bovis</i> BCG," <i>Kekkaku</i> (1994) 69(9):29-32.	
	**	Yamamoto S. et al., "Unique Palindromic Sequences in Synthetic Oligonucleotides Are Required to Induce IFN [correction of INF] and Augment IFN-mediated [correction of INF] Natural Killer Activity," <i>J. Immunol.</i> (1992) 148(12):4072-4076.	
	**	Yamamoto T. et al., "Ability of Oligonucleotides with Certain Palindromes to Induce Interferon Production and Augment Natural Killer Cell Activity is Associated with their Base Length," <i>Antisense Res. And Devel.</i> (1994) 4:119-123.	
	**	Yamamoto T. et al., "Lipofection of Synthetic Oligodeoxyribonucleotide having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity," <i>Microbiol. Immunol.</i> (1994) 38(10):831-836.	
	**	Yamamoto T. et al., "Synthetic Oligonucleotides with Certain Palindromes Stimulate Interferon Production of Human Peripheral Blood Lymphocytes <i>in vitro</i> ," <i>Jpn. J. Cancer Res.</i> (1994) 85:775-779.	
	**	Yew, et al., "Contribution of Plasmid DNA to Inflammation in the Lung After Administration of Cationic Lipid: pDNA Complexes" <i>Hum Gene Ther.</i> (1999) 20:10(2):223-234 ABSTRACT	
	***	Yew et al. "Reduced Inflammatory response to plasmid DNA vectors by elimination and inhibition of immunostimulatory CpG motifs" pp. 255-262 vol. 1, No. 3 2000	

EXAMINER	DATE CONSIDERED
----------	-----------------

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\* copies of these patents and patent applications are not enclosed pursuant to the waiver by the USPTO of the requirement under 37 C.F.R. 1.98 (a)(2)(i) for patent applications filed after June 30, 2003.

\*\*a copy of this reference is not provided as it was previously cited by or submitted to the office in one of the following prior applications, Serial No. 08/386,063 , filed 02/07/1995 , Serial No. 09/415,142 , filed 10/09/99 , Serial No. 10/690,495 , filed 10/21/03 and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

\*\*\* a copy of this reference is not provided as it was cited by Examiner in Serial No. 09/415,142 , filed 10/09/99